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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/739,457	12/17/2003	Hendrik-Jan Houthoff	570-29 PCT/US/CON	9335
23869	7590	05/24/2006	EXAMINER	
HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791			SWARTZ, RODNEY P	
			ART UNIT	PAPER NUMBER
			1645	
DATE MAILED: 05/24/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/739,457

Applicant(s)

HOUTHOFF ET AL.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Continued Examination Under 37 CFR 1.114**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 May 2006 has been entered.

Claims 1, 6, and 15 have been amended. The Terminal Disclaimer has been approved and entered.

2. Claims 1-16 are pending and under consideration.

### **Rejections Withdrawn**

3. The rejection of claims 1-16 under 35 U.S.C. 112, first paragraph, scope of enablement for all/other species of *Mycobacteria*, is withdrawn in light of claim amendments and applicants' arguments.

4. The rejection of claims 1-16 under the judicially created doctrine of obviousness-type double patenting as being patentable over claims 1-42 of U.S. Pat. No. 6,733,983 is withdrawn in light of the submitted Terminal Disclaimer.

### **Rejection Maintained**

5. The rejection of claims 1-16 under 35 U.S.C. 112, second paragraph, indefiniteness, is maintained.

Applicants argue that the amendment of claim 1 obviates the rejection.

The examiner has considered applicants' argument, but does not find it persuasive. As newly amended, one embodiment of claim 1 reads "A method for identifying a Mycobacterium

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species comprising the steps of: a) contacting one IMCRAC of a mycobacterial species with a sample of a body fluid of a human or animal individual; b) contacting at least one antibody, which is capable of reacting with a mycobacterial antigen of said mycobacterial species but does not cross-react with the one IMCRAC component, with said body fluid sample; c) detecting the presence of antigen-antibody complexes, and identifying the Mycobacterium species present in said body fluid sample.”

The claims remain indefinite because it is unclear how one detects any antigen-antibody complexes when utilizing an antibody which does not bind to the only antigen present, i.e., one IMCRAC.

### **Conclusion**

6. Claims 1-16 are not allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.


If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**RODNEY P SWARTZ, PH.D**  
PRIMARY EXAMINER  
Art Unit 1645

May 19, 2006